

U.S. Patent Application No. 10/681,352  
Amendment dated September 26, 2005  
Response to Office Action dated July 1, 2005

**REMARKS/ARGUMENTS**

Reconsideration and continued examination of the above-identified application are respectfully requested.

Claims 1, 4 - 7, 11, and 13 are amended, claims 15 - 18 are canceled without prejudice or disclaimer, and new claims 19 - 24 are added to the application. The amendment to the claims is editorial in nature and/or further defines what the applicant regards as the invention. Full support for the amendment can be found throughout the present application and the claims as originally filed, such as, for example, the description at pages 22 - 23 of the present specification. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

**Rejection of claims 1 - 14 under 35 U.S.C. § 112, first paragraph**

At page 2 of the Office Action, the Examiner rejected claims 1 - 14 under 35 U.S.C. § 112, first paragraph. In particular, the Examiner alleged that the specification is not enabling for cancer "curative" medicines. For the following reasons, this rejection is respectfully traversed.

Although the Applicants do not agree that the specification is not enabling for cancer curative medicines, in order to assist the Examiner, claims 1 and 4 - 7 recite cancer "treatment" medicines. Therefore, this rejection should be withdrawn.

**Various rejections of claims 1 - 18 under 35 U.S.C. § 112, second paragraph**

At page 3 of the Office Action, the Examiner rejected claims 1 - 18 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner alleged that it is unclear if the items in parentheses are part of the claimed subject matter. The Examiner further alleged that

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the phrases "have been determined," "have been analyzed," and "have been used" are indefinite as being grammatically improper. For the following reasons, this rejection is respectfully traversed.

Although the Applicants do not agree that the claims are indefinite, in order to assist the Examiner, claims 1, 11, and 13 are amended to remove items in parentheses and to provide greater grammatical clarity. Therefore, this rejection should be withdrawn.

Also, at page 3 of the Office Action, the Examiner rejected claims 1, 11, 13, 15, and 17 under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential steps including describing *in vitro* and/or *in vivo* screening to determine effective cancer curative methods and a step correlating the marker with the effectiveness of a cancer curative medicine. For the following reasons, this rejection is respectfully traversed.

Although the Applicants do not agree that the claims are incomplete, in order to assist the Examiner, claim 1 is amended to provide a step of screening a set of candidate compounds, and claims 11 and 13 are amended to provide a step of correlating a marker with the effectiveness of a cancer treatment. Therefore, this rejection should be withdrawn.

Also at page 3 of the Office Action, the Examiner rejected claims 1 - 14 as allegedly being incomplete for omitting a host or samples obtained from a host. For the following reasons, this rejection is respectfully traversed.

Although the Applicants do not agree that the claims are incomplete, in order to assist the Examiner, claims 1, 11, and 13 are amended to provide that polymorphic positions of amino acids and survival results are analyzed in a patient population, thereby relating the genetic material being analyzed to the source of the material. Claims 11 and 13 are amended to further provide a step of determining whether the amino acids at the polymorphic positions encoded by

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the listed genes of HLA or the listed genes of HLA, respectively, of a patient correlate with a variation that has a statistically significant relationship with a cancer treatment. Therefore, this rejection should be withdrawn.

At page 4 of the Office Action, the Examiner alleged that claim 7 is indefinite because the metes and bounds of the phrase "under a condition in which the interaction is possible" cannot be determined. For the following reasons, this rejection is respectfully traversed.

Although the Applicants do not agree that the claims are indefinite, in order to assist the Examiner, claim 7 is amended to specify that the interaction is between the candidate compounds and the three-dimensional structure. Therefore, this rejection should be withdrawn.

Also, at page 4 of the Office Action, the Examiner further alleged that claims 17 - 18 are indefinite because the phrase "the specified positions and the amino acids together with the base sequences have been used as a marker" does not particularly point out the chemical reactants for "clinical measuring reagents." The Examiner also alleged that there is insufficient antecedent basis for the limitation "wherein the variation of polymorphic positions" in line 5 of claim 15. The Examiner further rejected claims 17 - 18 as allegedly being incomplete for omitting chemical reactants. For the following reasons, this rejection is respectfully traversed.

Although the Applicants do not agree that these claims are indefinite or incomplete, in order to assist the Examiner, claims 15 - 18 are canceled and replaced by new claims 19 - 24. The new claims are directed to a composition comprising a polypeptide and do not recite a reagent. Therefore, the claims do not require a recitation of chemical reactants. Moreover, the claims provide antecedent basis for the recitation of "the polymorphic variation" as it occurs in claims 19 and 22. Therefore, this rejection should be withdrawn.

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**Rejection of claims 11, 13, 15 and 17 under 35 U.S.C. § 103(a) over Santamaria et al. (U.S. Patent No. 5,972,604)**

At pages 5 - 6 of the Office Action, the Examiner rejected claims 11, 13, 15, and 17 under 35 U.S.C. § 103(a) over Santamaria et al. (U.S. Patent No. 5,972,604). The Examiner alleged that Santamaria et al. discloses a method for determining the nucleic acid sequence of one or more polymorphic genes, including DRB1, DQB1 and DPB1 genes of HLA and discloses that sequence polymorphism analysis of these genes can be rapidly performed in any subject of unknown HLA type, referring to col. 9, lines 60 - 68 and col. 10, lines 1 - 16 of Santamaria et al. The Examiner further alleged that Santamaria et al. discloses positions of polymorphic amino acid sequences that include at least one of DRB1, DQB1 and DPB1 and addresses variations of the base sequence. The Examiner acknowledged that Santamaria et al. does not teach or suggest addressing a marker, but alleged that since Santamaria et al. discloses specific amino acid positions and base sequences that can be used for disease diagnosis, including cancer, the Santamaria et al. disclosure renders the marker obvious. The Examiner further alleged that it would be obvious to provide methods for evaluating cancer treatments and clinical measuring reagents because Santamaria et al. discloses method steps and starting reagents for diagnosing cancer and suggests treatments. For the following reasons, this rejection is respectfully traversed.

Santamaria et al. does not teach or suggest any method of evaluating cancer treatments by determining polymorphic variations that have a significant relationship with specific treatments in a patient population and then determining whether the polymorphic variation of a specific patient correlates with a such a variation as required by claims 11 and 13. Regarding the composition claims, now new claims 19 - 24, Santamaria et al. does not teach or suggest any composition of polymorphic variations that are selected as having a significant relationship with

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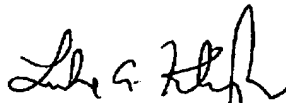
specific treatments. Accordingly, claims 11 and 13 and new claims 19 - 24 would not have been obvious over Santamaria et al. Therefore, this rejection should be withdrawn.

### **CONCLUSION**

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this Amendment, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account.

Respectfully submitted,



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